



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

022850 H212/1220
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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/945,805	01/06/98	006	MCGARRY, S	1635 12/20/00
First Named Applicant	MORISHITA,	35 USC 154(b) term ext. =	0 Days.	

TITLE OF INVENTION REMEDY FOR DISEASES ASSOCIATED WITH NF-KB

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	0018-0993-0P	514-044.000	WB4 UTILITY	NO	\$1240.00	03/20/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Exs Amdt/B

Notice of Allowability

Application No.

08/945,805

Examiner

Sean McGarry

Applicant(s)

MORISHITA ET AL.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12-13-00.
 2. ☒ The allowed claim(s) is/are 10-15.
 3. ☐ The drawings filed on _____ are acceptable as formal drawings.
 4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review(PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- | | |
|---|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>15</u> . | <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | <input checked="" type="checkbox"/> Other attachment. |

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Ex's Amdt/E
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Pereira on 12/13/00.

2. The application has been amended as follows:

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Claim ~~10~~^{1.} (amended). A method for treatment of NF-κB-associated diseases which comprises administering to an animal an effective amount of a [polynucleotide] polynucleotide [that binds to the] NF-κB chromosomal binding site decoy which antagonizes NF-κB-mediated transcription of a gene located downstream of [said] a NF-κB binding site wherein said polynucleotide comprises the 8th through the 17th nucleotide of SEQ ID NO: 1.

E²
Claim ~~11~~^{2.} (amended). The method according to claim ~~10~~^{1.} wherein the NF-κB-associated disease is selected from the group consisting of: an ischemic disease, an inflammatory disease, [or] and an autoimmune disease.

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Claim ~~13~~⁴ (amended). The method according to claim ~~10~~¹ wherein the NF-κB-associated disease is selected from the group consisting of: a reperfusion disorder in ischemic [diseases] disease, aggravation of [the] a prognosis of an organ transplantation [or organ surgery], aggravation of a prognosis of an organ surgery, [or] and post-PTCA restinosis.

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Claim ~~14~~⁵ (amended). The method according to claim ~~10~~¹ wherein the NF-κB-associated disease is selected from the group consisting of: a reperfusion disorder in ischemic heart [diseases] disease, aggravation of [the] a prognosis of a heart transplantation [or heart surgery], aggravation of a prognosis of a heart surgery, [or] and post PTCA restinosis.

Claim ~~15~~⁶ (amended). The method according to claim ~~10~~¹ wherein the NF-κB-associated disease is selected from the group consisting of: a cancer metastasis [or], a cancer invasion, [or] and cachexia.

3. The following is an examiner's statement of reasons for allowance: The instant invention is drawn to the treatment of diseases that are associated with NF-κB mediated gene expression via the administration of a specific NF-κB binding polynucleotide decoy. The specification provides *in vivo* models for reperfusion, metastasis, and cachexia. The references provided in the form 1449, filed 11/6/00, provide *in vivo* evidence for attenuation of myocardial cell infiltration and arterial neointimal formation, myocardial infarction inhibition, ischemia-reperfusion treatment,

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inhibition of cachexia, treating cerebral angiopathy and cerebral vasospasm, suppressed severity of collagen induced arthritis, attenuation of glomular inflammation, inhibition of intimal hyperplasia. The examples in the specification and the evidence in the references provided all use the specific polynucleotide inhibitor recited in the instant claims. Also taught in the specification is the preferred use of membrane fusing liposome constructs such as the use of Sendai virus. The evidence provided indicates the general applicability of NF- κ B inhibition in a broad range of disease states.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028.

Sean McGarry

December 14, 2000


SEAN MCGARRY
PATENT EXAMINER
TCL 1600

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ATTACHMENT TO AND MODIFICATION OF
NOTICE OF ALLOWABILITY (PTO-37)
(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored¹:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

¹ The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "Changes to Implement the Patent Business Goals", 65 Fed. Reg. 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 Off. Gaz. Pat. Office 77, 99, 110, 135, 139 (September 19, 2000).

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